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Spacer-K Modification

MAY 22 2008

510 (k) Summary

510(k) Summary

Applicant/consultant:	EXACTECH® INC. 2320 N.W. 66TH COURT GAINESVILLE, FLORIDA 32653 PHONE: (352) - 377 – 1140 FAX: (352) - 378 - 2617 CONTACT: Mike Simpson
Manufacturer/Submitter:	TECRES S.P.A. VIA ANDREA DORIA 37066 SOMMACAMPAGNA VERONA – ITALY FDA OWNER/OPERATOR ID #: 9033624
Date:	May 21, 2008
Trade/Proprietary model names:	SPACER-K TEMPORARY KNEE PROSTHESIS
Common name:	TEMPORARY KNEE SPACER WITH GENTAMICIN
Device classification name:	PROSTHESIS, KNEE, PATELLOFEMORAOTIBIAL, SEMI-CONSTRAINED, CEMENTED, POLYMER/METAL/POLYMER
Regulation number:	888.3560
Device class:	II
Classification panel:	ORTHOPAEDIC
Classification Product Code:	JWH

Spacer-K Modification
510(k) Summary Continued

DEVICE DESCRIPTION

The Spacer-K is a temporary device that mimics a "total knee prosthesis". The two-component unconstrained design incorporates a femur and tibial component, it's fully formed by gentamicin/polymethylmethacrylate (PMMA) bone cement.

INDICATIONS FOR USE

Spacer-K is indicated for temporary use (maximum 180 days) as an adjunct in total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process. Spacer-K is only indicated for an implantation period of 180 days or less. Because of the inherent mechanical limitations of the device material (gentamicin/polymethilmethacrylate), Spacer-K is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

SUBSTANTIAL EQUIVALENCE:

The modified Spacer-K device has the same design, incorporates the same materials, has equivalent performance and mechanical characteristics, and has the same shelf and packaging as the predicate Spacer-K device (K032522). Additionally, the modified Spacer-K device has a similar gentamicin release profile as that of the predicate Biomet Stage One Disposable Cement Spacer Mold for Temporary Knee Prosthesis with Reinforcement Stem (K050210) when used with predicate Biomet Cobalt G HV Bone Cement (K051532).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2008

Exactech, Inc.
% Mr. Xavier Sarabia
Director, Regulatory Affairs
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K062274
Trade/Device Name: Spacer K
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: February 22, 2008
Received: February 25, 2008

Dear Mr. Sarabia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Spacer-K Modification

Indications for Use

510(k) Number (if known): K062274

Device Name: Spacer-K

Indications for Use: Spacer-K is indicated for temporary use (maximum 180 days) as an adjunct in total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process.

Spacer-K is only indicated for an implantation period of 180 days or less. Because of the inherent mechanical limitations of the device material (gentamicin/polymethilmethacrylate), Spacer-K is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062274